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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,887	10/10/2001	Yoshinao Nagashima	214089US0CONT	4455

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MITCHELL, GREGORY W	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,887	NAGASHIMA ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,8,12-14,20,23,24,26-31,34,35 and 37-42* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,8,12-14,23,24,26-31,34,35 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed June 24, 2005. Claims 1, 4, 8, 14, 20, 23, 26, 28, 31, 34, 37 and 39 have been amended. Claims 3, 25, 32-33, 36 and 43-44 have been cancelled. Claims 1-2, 4-5, 8, 12-14, 20, 23-24, 26-31, 34-35 and 37-42 are pending. Claim 20 has been withdrawn from consideration. Claims 1-2, 4-5, 8, 12-14, 23-24, 26-31, 34-35 and 37-42 are examined herein.

Applicant's amendments are sufficient to overcome the 35 USC 112(1) new matter rejection of claims 1-5, 8, 12-14 and 21-44. Applicant's amendment is sufficient to overcome the objection to claim 8. Applicant's amendments and arguments are sufficient to overcome the 35 USC 103 rejection of claims 1-5, 8, 12-14 and 21-44. It is noted that in addition to Applicant's arguments, Examiner has relied on Buchbauer et al. (*Journal of Pharmaceutical Sciences*, 82(6), 660-4) in withdrawing the 35 USC 103 rejection wherein Binet et al. (*Therapie*, 27(5), 893-905) was utilized as the primary reference. Particularly, Applicant's argument that "the physiological activity of farnesol is reported to be dependent on the mode of administration and therefore there is no motivation to deviate from the oral and intraperitoneally modes of administration described" is convincing in view of Buchbauer et al. Buchbauer et al. teaches that farnesol is known in the art to *increase* motility when inhaled, indicating that it would *not* be suitable for *increasing* an ECG R-R interval or decreasing blood pressure because it would be expected to have a *stimulating* effect. See Abstract; p. 661. The following rejections now apply.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-5, 23-24, 26-27, 34-35 and 37-38 rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (USPN 4713291).

Sasaki et al. discloses the use of a composition comprising 5% cedarwood oil for giving comfortable sleep (col. 9, line 53-col. 10, line 36). Cederwood oil is disclosed to comprise between 3 and 14% cedrol (col. 6, lines 38-55). The assisted sleep is accomplished by allowing the composition to disperse into the air (col. 2, lines 37-51; col. 9, line 53-col. 10, line 36). Accordingly, administration is accomplished via inhalation.

It is noted that the odor limitation is directed to a composition having "an odor below a detectable threshold." Such a limitation is not the same as a composition that does not have an odor above a detectable threshold. Accordingly, any composition that has a detectable odor will, inherently, also have an odor below a detectable threshold because in order for a composition to have an odor above a detectable threshold, it must also have an odor below a detectable threshold.

It is noted that though Sasaki et al. does not teach increasing an ECG R-R interval or decreasing blood pressure, it does teach a method of assisting sleep. Discovery of a mechanism of action in a method of treatment is not inventive if the same

mechanism must have been inherently present, whether or not said mechanism was disclosed in the prior art. In the present case, since the claims and the prior art are directed to the same treatment, the mechanisms by which said treatment occurred must have been present.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 12, 28-29 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. (USPN 4713291).

Sasaki et al. discloses the use of a composition comprising 5% cedarwood oil for giving comfortable sleep (col. 9, line 53-col. 10, line 36). Cederwood oil is disclosed to comprise between 3 and 14% cedrol (col. 6, lines 38-55). The assisted sleep is accomplished by incorporating the fibers of bedding, etc., allowing the composition to disperse into the air (col. 1, lines 7-18; col. 2, lines 37-51; col. 9, line 53-col. 10, line 36). Accordingly, administration is accomplished via inhalation. Sasaki et al. teaches using the adsorption of such compositions onto fibers as known in the art, but that the composition is readily removed from such fibers by washing (col. 1, lines 20-33). Sasaki et al. does not specifically teach the air concentration or the spraying of the composition onto bedding.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the composition and fibers whereby the sesquiterpene alcohol was present in the air in the concentrations claimed because Sasaki et al. teaches that the volatile components of the composition are effective by diffusing into the air. Accordingly, Sasaki et al. teaches the presence of the cedrol in the air in general. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to one of ordinary skill in the art at the time of the invention to adsorb the composition (by spraying or other known means) onto the bedding fibers rather than incorporating the composition therein because Sasaki et al. teaches the adsorption of such compositions onto such fibers as known in the art. One would have been motivated to coat the bedding fibers rather than incorporating the compositions therein because of an expectation of success in preparing a bedding wherein the composition could be removed by washing, if so desired, as taught by Sasaki et al.

Claims 13-14, 30-31 and 41-42 rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. (USPN 4713291) as applied to claims 8, 12, 28-29 and 39-40 above, and further in view of Liu et al. (USPN 5195514).

Liu et al. teaches a medicinal vaporizer which produces steam and has a heating element (Abstract; col. 1, lines 56-65). It is taught that it is known in the art to mix the

water to be humidified with medication so that the vapor form may be inhaled (col. 1, lines 12-17). It is also taught that it is known in the art to administer the medicinal vapor to one person at a time via the use of a mask or to entire rooms so that multiple people may breath the medicated vapor (col. 1, lines 18-49).

It would have been obvious to one of ordinary skill in the art to administer the farnesol composition of Binet et al. and Albaugh by using a medicinal vaporizer as instantly claimed because (1) Sasaki et al. teaches assisting sleep via the inhalation of volatile components of a composition comprising cedrol; and (2) Liu et al. teaches that the inhalation of medicines may be achieved in vapor form via the use of humidifiers. One would have been motivated to administer the composition of Sasaki et al. in a method as instantly claimed because of an expectation of success in administering the composition to aid sleep via the inhalation of the volatiles therein, as taught by Sasaki et al.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendments and arguments are sufficient to overcome the rejections set forth in the Office Action dated February 14, 2005, for the reasons set forth above.

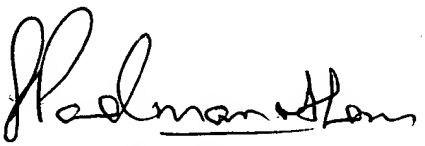
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER